

**Remarks**

**A. Pending Claims**

Claims 246-571 are currently pending. Claims 1-12, 29-70, 74-95, 99-140, 146-154, 157-165, and 168-245 have been cancelled. Claims 1-12, 29-36, 43, 45-70, 74-95, 99-138, 146-154, 157-165, 168-169, 177-178, 186-187, 195-230, 233, 235, 239, and 243-245 are rejected. Claims 37-42, 44, 139, 140, 170-176, 179-185, 188-194, 231, 232, 234, 236-238, and 240-245 are objected to. Claims 246-571 are new.

**B. The Claims Are Not Anticipated By Deslauriers Pursuant To 35 U.S.C. § 102(b)**

The Office Action includes a rejection of claims 1-5, 8-12, 29-35, 45-47, 49, 50, 54-70, 74, 75, 79-95, 104-116, 119-138, 146-154, 157-165, 168, 169, 186, 187, 195-216, 218, 220-230, 233, and 235 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,255,678 to Deslauriers et al. (“Deslauriers”). Applicant respectfully disagrees with these rejections.

The standard for “anticipation” is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81, 91 (Fed. Cir. 1986); *In re Donahue*, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).

The Office Action states:

Deslauriers et al disclose in Figure 2 a balloon device 20 that is shaped and sized to fit within and occupy a patient’s left ventricle 40 when inflated. The device further includes a tube 23 in fluid communication with the balloon 20, a valve 24, pressure gauge (column 8, line 65) and syringe 26. The purpose for

which applicant intends the device to be used (i.e. a “shaper”) fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers et al.

Applicant respectfully disagrees that the purpose for which Applicant intends the device to be used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers; however, in order to expedite prosecution of the present application Applicant has canceled the rejected claims 1-5, 8-12, 29-35, 45-47, 49, 50, 54-70, 74, 75, 79-95, 104-116, 119-138, 146-154, 157-165, 168, 169, 186, 187, 195-216, 218, 220-230, 233, and 235.

**C. The Claims Are Not Anticipated By Dor Pursuant To 35 U.S.C. § 102(b)**

The Office Action included a rejection of claims 1, 2, 36, 43, 45-46, 48-50, 54-58, 64-65, 74-75, 79-83, 86, 90, 146-149, 153, 157-160, 164, 168-169, 186-187, and 195-214 under 35 U.S.C. 102(b) as anticipated by “Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities,” J. Cardiac Surg. 199:14:46-52) to V. Dor et al (“Dor”). Applicant respectfully disagrees with these rejections.

The Office Action states:

Note Figure 2 and the second column of page 48 which discloses the repair of a patient’s heart wherein an appropriately shaped balloon is inserted into the patient’s left ventricle and inflated to the appropriate size (volume) (and inherently the appropriate shape), the left ventricle is reformed over the balloon and the appropriate sized patch is determined from the ventricle reconstructed over the balloon, the balloon is then deflated and removed and the opening closed with the patch.

Applicant respectfully disagrees that Dor anticipates the invention as claimed by Applicant; however, in order to expedite prosecution of the present application Applicant has canceled the

rejected claims 1, 2, 36, 43, 45-46, 48-50, 54-58, 64-65, 74-75, 79-83, 86, 90, 146-149, 153, 157-160, 164, 168-169, 186-187, and 195-214.

**D. The Claims Are Not Obvious over Deslauriers in View of Hillegass, Kovacs, and Cook Pursuant To 35 U.S.C. § 103(a)**

The Office Action includes rejections of claims 6, 7, 57, 58, 82, 83, 99-103, 108, 109, 117, 118, 131, 132, 177, and 178 under 35 U.S.C. 103(a) as obvious over Deslauriers in view of U.S. Patent No. 4,817,637 to Hillegass et al. ("Hillegass"), U.S. Patent No. 5,749,839 to Kovacs ("Kovacs"), and U.S. Patent No. 5,964,806 to Cook et al ("Cook"). Applicant respectfully disagrees with these rejections.

In order to reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 USPQ 173, 177-178 (CCPA 1967). Obviousness can only be established by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

The Office Action states:

Deslauriers et al indicates that the balloon member is filled with a saline solution rather than the claimed silicone gel. The prior art, however, is replete with teachings that silicone gel may conventionally be used in place of saline for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel rather than saline for the balloon inflation fluid as is well known in the art would have been obvious to the ordinary skilled artisan. In regards to claims 57, 58, 82, 83, 108, 109, 131, and 132, to the extent that one interprets the fluid to be positively claimed, the present rejection

applies.

Applicant respectfully disagrees that the rejected claims are obvious in light of the cited art; however, in order to expedite prosecution of the present application Applicant has canceled the rejected claims 6, 7, 57, 58, 82, 83, 99-103, 108, 109, 117, 118, 131, 132, 177, and 178.

**E. The Claims Are Not Obvious over Deslauriers Pursuant To 35 U.S.C. § 103(a)**

The Office Action includes a rejection of claims 51-53 and 76-78 under 35 U.S.C. 103(a) as obvious over Deslauriers. Applicant respectfully disagrees with these rejections.

The Office Action states:

One of ordinary skill in the art would have found the manufacture of the Deslauriers et al device with the particular thickness dimension claimed obvious as a matter of routine.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 51-53 and 76-78; however, in order to expedite prosecution of the present application Applicant has canceled the rejected claims 51-53 and 76-78.

**F. The Claims Are Not Obvious over Dor Pursuant To 35 U.S.C. § 103(a)**

The Office Action includes a rejection of claims 3-5, 36, 43, 47-48, 51-52, 59-60, 76-77, 84-85, 150-151, 161-162, 168-169, 186-187, 215-217, 219-225, 229, 230, 233-235, 239, and 243-245 under 35 U.S.C. 103(a) as obvious over Dor. Claims 146-156 have been cancelled. Applicant respectfully disagrees with these rejections.

The Office Action states:

V. Dor et al fail to disclose that the balloon once fully inflated that it cannot be substantially further expanded or that the balloon maintains its shape while being inflated, however, one of ordinary skill in the art would have found such limitations obvious in the design and construction of the disclosed balloon. The ordinarily skilled artisan would have been motivated to use a balloon that resisted further filling once full so as to not provide for too large of a size during the V. Dor et al procedure and certainly the ordinarily skilled artisan would desire a balloon that maintained its shape during this critical open heart surgery. In regard to claims 51, 52, 76, and 77, the claimed wall thickness for the balloon fall well within a range one of ordinary skill in the art would have found to have been obvious in constructing the V. Dor et al balloon.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 3-5, 36, 43, 47-48, 51-52, 59-60, 76-77, 84-85, 150-151, 161-162, 168-169, 186-187, 215-217, 219-225, 229, 230, 233-235, 239, and 243-245; however, in order to expedite prosecution of the present application Applicant has canceled the rejected claims 3-5, 36, 43, 47-48, 51-52, 59-60, 76-77, 84-85, 150-151, 161-162, 168-169, 186-187, 215-217, 219-225, 229, 230, 233-235, 239, and 243-245.

**G. The Claims Are Not Obvious over Dor in View of Hillegass, Kovacs, and Cook Pursuant To 35 U.S.C. § 103(a)**

The Office Action includes a rejection of claims 6, 7, 57, 58, 82, 83, 99, 100, 177, and 178 under 35 U.S.C. 103(a) as obvious over Dor in view of Hillegass, Kovacs, and Cook. Applicant respectfully disagrees with these rejections.

The Office Action states:

V. Dor et al fails to disclose what type of fluid is used to inflate the

disclosed balloon. The prior art, however, is replete with teachings that silicone gel may conventionally be used for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel for the balloon inflation fluid as is well known in the art would have been obvious to the ordinarily skilled artisan. In regard to claims 57, 58, 82, and 83, to the extent that one interprets the fluid to be positively claimed, the present rejection applies.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 6, 7, 57, 58, 82, 83, 99, 100, 177, and 178; however, in order to expedite prosecution of the present application Applicant has canceled the rejected claims 6, 7, 57, 58, 82, 83, 99, 100, 177, and 178.

**H. The Claims Are Not Obvious over Dor in View of Deslauriers Pursuant To 35 U.S.C. § 103(a)**

The Office Action includes a rejection of claims 8-12, 32-35, 61-70, 87-89, 91-95, 152, 154, 163, 165, 218, and 223-228 under 35 U.S.C. 103(a) as obvious over Dor in view of Deslauriers. Applicant respectfully disagrees with these rejections.

The Office Action states:

In regard to claims 8-12, 61-63, 87-89, 152, and 163, V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon. Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and syringe are all desirable for controlling the inflation of a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V. Dor et al balloon would have been obvious to one of ordinary skill in the art. In regard to claims 32-35, 64, 66-70, 91-95, 154, and 165, V. Dor et al fail to disclose the actual shape of the disclosed balloon. Deslauriers et al, however, teaches that it is desirable to form left ventricle balloons in the shape of a left

ventricle which may be either ellipsoidal shape as in Figure 9 or drop/pear/cone shaped as in Figure 10. To have shaped the V. Dor et al balloon so that it was the shape of the left ventricle as taught by Deslauriers et al would have been obvious to one of ordinary skill in the art.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 8-12, 32-35, 61-70, 87-89, 91-95, 152, 154, 163, 165, 218, and 223-228; however, in order to expedite prosecution of the present application Applicant has canceled the rejected claims 8-12, 32-35, 61-70, 87-89, 91-95, 152, 154, 163, 165, 218, and 223-228.

**I. The Claims Are Not Obvious over Dor in View of Hillegass, Kovacs, and Cook and in Further View of Deslauriers Pursuant To 35 U.S.C. § 103(a)**

The Office Action includes a rejection of claims 101-103 under 35 U.S.C. 103(a) as obvious over Dor in view of Hillegass, Kovacs, and Cook and in further view of Deslauriers. Applicant respectfully disagrees with these rejections.

The Office Action states:

V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon. Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and a syringe are all desirable for controlling the inflation of a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V. Dor et al balloon would have been obvious to one of ordinary skill in the art.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 101-103; however, in order to expedite prosecution of the present application Applicant has canceled the rejected claims 101-103.

**J. Support for New Claims**

Claims 246-571 are new. Applicant submits that the new claims add no new matter. The Office Action states that claims 37-42, 44, 139-140, 170-176, 179-185, 188-194, 234, 231-232, 236-238, and 240-245 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New independent claim 246 includes features from objected to cancelled dependent claim 44 including all of the limitations of the base claim and any intervening claims. New independent claim 254 includes features from objected to cancelled dependent claim 41 including all of the limitations of the base claim and any intervening claims. New independent claim 262 includes features from objected to cancelled dependent claim 37 including all of the limitations of the base claim and any intervening claims. New independent claim 270 includes features from objected to cancelled dependent claim 176 including all of the limitations of the base claim and any intervening claims. New independent claim 278 includes features from objected to cancelled dependent claim 174 including all of the limitations of the base claim and any intervening claims. New independent claim 286 includes features from objected to cancelled dependent claim 170 including all of the limitations of the base claim and any intervening claims. New independent claim 294 includes features from objected to cancelled dependent claim 185 including all of the limitations of the base claim and any intervening claims. New independent claim 302 includes features from objected to cancelled dependent claim 183 including all of the limitations of the base claim and any intervening claims. New independent claim 310 includes features from objected to cancelled dependent claim 179 including all of the limitations of the base claim and any intervening claims. New independent claim 318 includes features from objected to cancelled dependent claim 194 including all of the limitations of the base claim and any intervening claims. New independent claim 326 includes features from objected to cancelled dependent claim 192 including all of the limitations of the base claim and any intervening claims.

New independent claim 334 includes features from objected to cancelled dependent claim 188 including all of the limitations of the base claim and any intervening claims. New independent claim 342 includes features from objected to cancelled dependent claim 245 including all of the limitations of the base claim and any intervening claims. New independent claim 372 includes features from objected to cancelled dependent claim 243 including all of the limitations of the base claim and any intervening claims. New independent claim 402 includes features from objected to cancelled dependent claim 231 including all of the limitations of the base claim and any intervening claims. New independent claim 457 includes features from objected to cancelled dependent claim 236 including all of the limitations of the base claim and any intervening claims. New independent claim 486 includes features from objected to cancelled dependent claim 237 including all of the limitations of the base claim and any intervening claims. New independent claim 515 includes features from objected to cancelled dependent claim 238 including all of the limitations of the base claim and any intervening claims. New independent claim 544 includes features from objected to cancelled dependent claim 240 including all of the limitations of the base claim and any intervening claims.

New claims 430 and 444 include features from objected to canceled dependent claims 139 and 140 respectively as objected in the Office Action mailed February 19, 2004, before Applicant's amendment in Applicant's submitted response to the Office Action mailed February 19, 2004, including all of the limitations of the base claim and any intervening claims. As such, Applicant submits that new claims 246, 254, 262, 270, 278, 286, 294, 302, 310, 318, 326, 334, 342, 372, 402, 430, 444, 457, 486, 515, and 544 and the claims dependent thereon, are in condition for allowance.

Inventors: Murphy et al.  
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**K. Conclusion**

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

A fee authorization form is included to cover additional claims fees. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any additional fees are required, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-00300/EBM.

Respectfully submitted,

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